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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,300	10/26/2001	Steven E. Ealick	UAB-20702/22	2920
7590 04/21/2004 Gifford, Krass, Groh, Sprinkle, Anderson & Citkowski, P.C. Suite 400 280 N. Old Woodward Avenue Birmingham, MI 48009-5394			EXAMINER RAMIREZ, DELIA M	
			ART UNIT 1652	PAPER NUMBER
DATE MAILED: 04/21/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,300	EALICK ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Application

Claims 1-56 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Leishmania donovani* nucleoside hydrolase, classified in class 435, subclass 195.
 - II. Claims 1-2, 4, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Trichomonas vaginalis* purine nucleoside phosphorylase, classified in class 435, subclass 193.
 - III. Claims 1-3, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Trypanosoma cruzi* nucleoside hydrolase, classified in class 435, subclass 195.
 - IV. Claims 1-2, 4, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Schistosoma mansoni* purine nucleoside phosphorylase, classified in class 435, subclass 193.
 - V. Claims 1-3, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Leishmania tropica* nucleoside hydrolase, classified in class 435, subclass 195.
 - VI. Claims 1-3, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Crithidia fasciculata* nucleoside hydrolase, classified in class 435, subclass 195.
 - VII. Claims 1-3, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Aspergillus* nucleoside hydrolase, classified in class 435, subclass 195.
 - VIII. Claims 1-3, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Penicillium* nucleoside hydrolase, classified in class 435, subclass 195.

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- IX. Claims 1-2, 4, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Erwinia carotovora* purine nucleoside phosphorylase, classified in class 435, subclass 193.
- X. Claims 1-2, 4, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Helix pomatia* purine nucleoside phosphorylase, classified in class 435, subclass 193.
- XI. Claims 1-2, 4, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Ophiodon elongatus* purine nucleoside phosphorylase, classified in class 435, subclass 193.
- XII. Claims 1-2, 4, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Salmonella typhimurium* purine nucleoside phosphorylase, classified in class 435, subclass 193.
- XIII. Claims 1-2, 4, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Bacillus subtilis* purine nucleoside phosphorylase, classified in class 435, subclass 193.
- XIV. Claims 1-2, 4, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Clostridium* purine nucleoside phosphorylase, classified in class 435, subclass 193.
- XV. Claims 1-2, 4, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Mycoplasma* purine nucleoside phosphorylase, classified in class 435, subclass 193.
- XVI. Claims 1-3, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Trypanosoma gambiense* nucleoside hydrolase, classified in class 435, subclass 195.

- XVII. Claims 1-2, 4, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Trypanosoma brucei* purine nucleoside phosphorylase, classified in class 435, subclass 193.
- XVIII. Claims 1-2, 4, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *Sulfolobus solfataricus* 5'-methylthioadenosine phosphorylase, classified in class 435, subclass 193.
- XIX. Claims 1-3, 5, 7-8, 14, 19-20, 22, 27, 33, drawn in part to a polynucleotide encoding a mutant *E. coli* 5'-methylthioadenosine/S-adenosyl homocysteine nucleosidase (nucleoside hydrolase), classified in class 435, subclass 195.
- XX. Claims 1-2, 4, 6-7, 9-10, 11-15, 16-21-22-26, 27-32, 33, 54, 56, drawn in part to a polynucleotide encoding the mutant *E. coli* purine nucleoside phosphorylase of SEQ ID NO: 2 or 4, classified in class 435, subclass 193.
- XXI. Claims 34-46, drawn to a process for impairing a cell with the polynucleotide of SEQ ID NO: 1 or SEQ ID NO: 3, classified in class 435, subclass 15.
- XXII. Claims 47-48, drawn to a process for impairing a cell with the polypeptides of SEQ ID NO: 2 or SEQ ID NO: 4, classified in class 435, subclass 15.
- XXIII. Claims 49-53, 55, drawn to the mutant *E. coli* purine nucleoside phosphorylases of SEQ ID NO: 2 or 4, classified in class 435, subclass 193.

The inventions are distinct, each from the other because of the following reasons:

2. Groups I-XX and XXIII each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The DNAs in Groups I-XX each comprise unrelated nucleic acid sequences whereas the proteins of Group XXIII comprise amino acid sequences. The DNAs of Group XX have other uses besides encoding the proteins of Group XXIII, such as a hybridization probe or in gene

therapy. The protein from Group XXIII can be used in materially different methods such as to make antibodies or in therapeutic/diagnostic methods. Further, the proteins of Group XXIII can be prepared by processes which are materially different from recombinant expression of the DNA of Group XX, such as by chemical synthesis, or by isolation and purification from natural sources.

3. Inventions XX and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Invention XX can be used to recombinantly produce the protein of Invention XXIII as well as in the process of Invention XXI.

4. Inventions XXIII and XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Invention XXIII can be used to elicit antibodies as well as in the process of Invention XXII.

5. Inventions XX and XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the DNA of Invention XX is neither used nor made by the method of Invention XXII.

6. Inventions XXIII and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the proteins of Invention XXIII are neither used nor made by the method of Invention XXI.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

9. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting

rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
April 9, 2004


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
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